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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,477

08/22/2006

Torsten Branderburger

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07/08/2008

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EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

07/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/550,477	<b>Applicant(s)</b> BRANDERBURGER ET AL.	
	<b>Examiner</b> Adam Marcetich	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Germany 103 13 760.2, filed on 27 March 2003 has been received.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Knierbein (US Patent 6,364,143).
4. Regarding claim 1, Knierbein discloses a connector for packings containing medical liquids, particularly infusion, transfusion or enteral bags, with:

a connecting part with a passage for accommodating a spike for withdrawal of the liquid (column 3, lines 32-54 and Fig. 1, base body 2 having passage);

a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (column 3, lines 32-54 and Figs. 1-2, protective cap 5 closing passage in base body 2);

characterized in that the connecting part has an elastically deformable pinching-off part designed as a tubular portion (column 3, lines 32-54 and Fig. 1, tubular upper part 4);

with a noncircular cross section (column 3, lines 32-54 and Fig. 1, base body 2 comprising radially projecting wing-like pieces 7 and 8 with non-circular cross section); and

in that the pinching-off part merges into a base part which widens to both sides and which can be integrated in the packing (column 3, lines 32-54 and Fig. 1, boat-shaped lower part 3).

5. Regarding claim 5, Knierbein discloses a connector characterized in that the closure part has a cap-shaped bottom part (col. 3, lines 41-49 and Fig. 1, flange 10. Examiner interprets the language “cap-shaped” broadly to include a hollow, cylindrical shape. Examiner notes that a more specific definition of “cap-shaped” does not appear in the immediate specification.);

6. which is adjoined, via an annular break zone (col. 3, lines 46-54 and Fig. 1, annular fracture zone 12);

7. by a top part that can be broken off (col. 3, lines 46-54 and Fig. 1, wings 13 and 14). Examiner interprets the limitation of "that can be broken off" broadly to include wings 13, 14 being removed with protective cap 5.

8. Regarding claim 6, Knierbein discloses a connector characterized in that the top part that can be broken off is designed as a flat grip piece (Fig. 1, wings 13 and 14 forming a flat grip piece).

9. Regarding claim 9, Knierbein discloses a connector characterized in that the base part is designed in the shape of a boat (col. 3, lines 32-40 and Fig. 1, boat-shaped lower part 3 having boat-shape).

10. Regarding claim 10, Knierbein discloses a packing for medical liquids, particularly an infusion, transfusion or enteral bag, having at least one connector as claimed in claim 1 (col. 3, lines 32-40, conventional collapsible bag for medicinal liquids).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knierbein (US Patent 6,364,143) in view of Burns (US Patent 5,494,170).

14. Regarding claim 2, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks a snap fit as claimed [claim 2]. Burns discloses a closure part and connecting part secured with a snap fit (column 2, lines 61-67 and column 3, lines 13-23, Fig. 1, cam ring 4 and cooperating cam follower ring 16 forming snap-fit). Burns provides the advantage of temporary closure between a cover and medicament dispenser. This allows a user to reseal the container after withdrawing fluid with a piercing member. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the snap fit as taught by Burns in order to temporarily close a medicament dispenser.

15. Regarding claim 3, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks a self-sealing membrane arranged between a connecting part and closure part as claimed [claim 3]. Burns discloses a self-sealing membrane (column 2, lines 8-11, 53-58, Fig. 1 stopper 12). Burns provides the

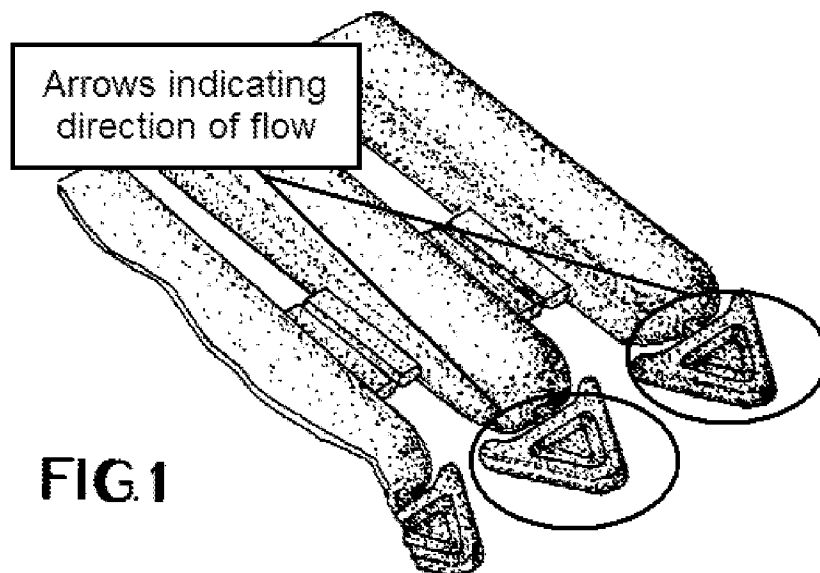
advantage of a repeatedly pierceable membrane that allows for multiple withdrawals of fluid or medicament with a piercing member. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the self-sealing membrane as taught by Burns in order to provide multiple sample withdrawals from a container.

16. Regarding claim 4, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part as claimed [claim 4]. Burns discloses a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part (column 2, lines 53-58 and Fig. 1, stopper 12 depicted as held between tube 1 and shield 11). Burns provides the advantage of simple construction in addition to multiple withdrawals as discussed for claim 3 above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the clamped, self-sealing membrane as taught by Burns in order to provide simple construction and multiple sample withdrawals.

17. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knierbein (US Patent 6,364,143) in view of LeMarr et al. (US D456,507).

18. Regarding claims 7 and 8, Knierbein discloses the invention as substantially claimed, see above. However, Knierbein lacks an arrow designed as a recess and/or as a raised structure as claimed [claims 7 and 8]. LeMarr discloses a nebulizer vial

comprising an arrow designed as a recess and/or as a raised structure (see annotated Fig. 1 below). LeMarr provides the advantage of showing a user where fluid will exit a container when opened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Knierbein as discussed with the arrow as taught by LeMarr in order to instruct a user.



Annotated Fig. 1 of LeMarr et al. (US D456,507)

### ***Response to Amendment***

19. Objections to the abstract and claims 5-10 applied in the Office Action dated 26 December 2007 are withdrawn in view of the amendments filed 26 March 2008. All pending claims 1-10 are treated on the merits.



***Response to Arguments***

20. Applicant's arguments filed 26 March 2008 have been fully considered but they are not persuasive.

21. Applicant asserts that the upper tubular part of Knierbein cannot be elastically deformable, since this would prevent screwing into a coupler nut. Examiner notes that the language "elastically deformable" is not given special meaning in the immediate specification, therefore it is interpreted broadly to include plastics capable of being deformed elastically. For example, upper part 4 of Knierbein is disclosed as being injection molded (col. 4, lines 50-55).

22. Applicant asserts that the connecting part described in Knierbein screws into the coupler nut, so it cannot have a noncircular cross-section, since such a noncircular cross-section would prevent the formation of a seal. To clarify, Examiner interprets base body 2 of Knierbein as the claimed "connecting part" of claim 1. Here, the lower portion of base body 2 is relied upon for the limitation of a non-circular cross section. In other words, Examiner interprets base body 2 of Knierbein as including both a circular and non-circular cross section.

23. Further, Applicants submit that the Office has misread Knierbein, since the radially projecting wing-like pieces do not form the "connecting part" of the connector disclosed by Knierbein. Rather, these radially projecting wing-like pieces form the base part of the connector, linking the connector to the container. In contrast, in the Application, the actual connecting part has the noncircular cross-section. Examiner

notes that the limitation of radially projecting wing-like pieces do not appear in the claims. Regarding a claimed “top part (8) / flat grip piece (8)” of claims 5 and 6, it is the Examiner’s position that wings 13 and 14 of Knierbein are substantially broken off along with protective cap 5 during use. In other words, wings 13 and 14 are separated from base body 2 during use. See discussion of claims 5 and 6 above. Examiner notes that limitations are not to be imported from the specification.

24. Applicant asserts that Burns fails to remedy shortcomings of Knierbein, since Burns lacks the limitation in claim 1 of a container comprising an elastically deformable pinching-off part with a noncircular cross- section. Examiner notes that Knierbein is relied upon for the limitation of an elastically deformable pinching-off part with a noncircular cross- section.

25. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Knierbein; Bernd                      US 6709424
- ❖ Dark; Richard C. G.                  US 6330959
- ❖ Versluys; Robert Thor              US 6752264
- ❖ Fontana; Antonio et al.              US 4951822
- ❖ Kimber; Michael B. et al.          US 5409125
- ❖ Meierhoefer; Eugene J.              US 4502616
- ❖ Chiesi; Paolo et al.                  US 6116449
- ❖ Larenz; Joachim et al.              US 3917120
- ❖ Harris; Reed A. et al.                US D358466

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761